

TESTIMONY OF
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BEFORE THE
ENVIRONMENT AND PUBLIC WORKS COMMITTEE
UNITED STATES SENATE

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Good morning, Madam Chair and Members of the Committee. I am Benjamin H. Grumbles, Assistant Administrator for Water at the United States Environmental Protection Agency (EPA). One of Administrator Stephen L. Johnson's key principles for the Agency is using the best available science for decision-making to accelerate the pace of environmental protection in our country while maintaining our country's economic competitiveness.

We appreciate the opportunity to provide you with information about our on-going efforts to determine the need for managing potential risks posed by perchlorate and trichloroethylene.

We are working with other federal agencies to gather and understand data needed to inform our decision-making. We are committed to using the best science to ensure that our policies continue to protect public health and the environment.

Perchlorate Research and Risk Management for Contaminated Sites

EPA has been working on the science related to perchlorate for more than ten years. In 2003, EPA sent its January 2002 external review draft of the perchlorate risk assessment to the National Academy of Sciences (NAS) for review. The NAS panel released a report in January 2005 which recommended that the Agency use a reference dose (RfD) of 0.0007 mg/kg/day (0.7 µg/kg/day) based on a human study (Greer et al., 2002). The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of adverse effects during a lifetime. EPA endorsed their recommendation and used the NAS panel report "*Health Implications of Perchlorate Ingestion*" as the basis for establishing its RfD which was subsequently posted to the Integrated Risk Information System (IRIS) database in February 2005.

In carrying out their analysis, the NAS recommended the use of a human study (Greer et al., 2002) as the principal study. Because this study was based on healthy adult men and women, an uncertainty factor of 10 was applied to the no observed effect level (NOEL) identified from the Greer data to protect the most sensitive population, i.e., the fetuses of pregnant women who might have hypothyroidism or iodide deficiency. The NAS also indicated that deriving the RfD to prevent a nonadverse precursor effect, which would precede an adverse effect, as was done here, is a conservative and health-protective approach to perchlorate risk assessment.

In January 2006, EPA issued guidance for contaminated sites which recommended a revised preliminary remediation goal (PRG) of 24.5 ppb perchlorate in water. The PRG was calculated from EPA's RfD using standard exposure values of 70 kg body weight and 2 liters of water consumed per day. This calculation provides the drinking water equivalent level, assuming no other sources of perchlorate exposure.

PRGs are, however, not final cleanup levels, but are the starting point for identifying site-specific goals. In accordance with the National Contingency Plan, PRGs should be modified, as necessary, as more information becomes available at specific sites. This may include assessing factors such as actual and potential exposure pathways through environmental media and actual and potential exposure routes.

In addition, if a state has promulgated a drinking water standard for perchlorate (e.g., Massachusetts adopted 2 ppb as a drinking water standard), that value would be considered an Applicable or Relevant and Appropriate Requirement (ARAR) and used as the ground water cleanup level for sites in that state.

Perchlorate Risk Management for Drinking Water

The Agency has also been working to evaluate the potential risks posed by perchlorate in drinking water. The Agency has placed a high priority on making a regulatory determination for perchlorate as soon as possible and intends to make a final determination by the end of this year.

The Safe Drinking Water Act (SDWA) has an established process for determining if unregulated contaminants pose a sufficient risk to public health to warrant regulation. The law

requires the Agency to develop a Contaminant Candidate List (CCL), which is a list of unregulated contaminants that may require regulation. Perchlorate was placed on the first CCL which was released in 1998 and carried on to the second CCL which was published in February of 2005. It has also been included on the draft third CCL which was published this past February. Every five years, EPA must determine whether or not to regulate at least five contaminants from the list. EPA may also decide at any time to regulate a contaminant (whether on the list or not) if we believe it is necessary to do so to protect health.

In making a determination to regulate a contaminant under the SDWA, the law requires EPA to consider three questions:

- Is the contaminant likely to cause an adverse effect on the health of persons?
- Is the contaminant known or likely to occur in public water systems at a frequency and level of public health concern?
- In the sole judgment of the Administrator, does regulation present a meaningful opportunity to reduce risk for persons served by public water systems?

When the Agency issued the first set of regulatory determinations for nine contaminants on the first CCL in 2003, we did not have sufficient information to make a regulatory determination for perchlorate. The Agency's risk assessment and RfD value had not yet been finalized and we were continuing to collect occurrence data from public water systems under the first round of unregulated contaminant monitoring.

In May 2007, the Agency issued a Federal Register Notice with preliminary regulatory determinations for 11 contaminants on the second CCL. The Notice also indicated that the Agency was not making a preliminary determination on perchlorate at that time because of the need to more fully characterize and understand perchlorate exposure. The Notice provided an extensive update on the Agency's review of perchlorate, including a summary of recent research, and requested comment on approaches the Agency has under consideration to help arrive at a final decision.

Health Effects

Based on the RfD, the Agency has sufficient information on health effects to answer the first question needed to inform a regulatory determination. However, as with any chemical, the Agency is continuing to review new research findings on perchlorate as they become available.

Occurrence in Drinking Water

To support our regulatory development process, the Agency requires short-term monitoring for specific contaminants under the Unregulated Contaminant Monitoring Rule program (UCMR). During the first round of this program, which included monitoring for 26 contaminants, 3,858 water systems monitored for perchlorate during a one-year period between 2001 and 2003. This monitoring was designed to provide an assessment of perchlorate occurrence in public water supplies that was representative of community water systems throughout the country.

Perchlorate was detected at levels above the minimum reporting level of 4 parts per billion (ppb) in approximately 2 percent of the more than 34,000 samples analyzed. The average concentration of the detected values was 9.8 ppb and the median concentration was 6.4 ppb. The samples in which perchlorate was detected were collected from 160 of 3,858 public water systems (4% of systems) located in 26 states and 2 territories.

We have determined that the existing data on the occurrence of perchlorate in public water supplies is sufficient to support our regulatory decision-making and, as such, it is not necessary to conduct additional perchlorate monitoring under the second round of the UCMR program, which began for 25 new contaminants this year. Additionally, monitoring under the second UCMR would not be completed until 2010 and the Agency intends to make a final determination in 2008. If necessary, EPA can require additional monitoring at a later time if new information indicates that additional sampling is warranted. If EPA determines that federal regulation of perchlorate in drinking water is necessary, on-going compliance monitoring of perchlorate would be part of any new standard.

Relative Source Contribution and Other Sources of Exposure

Before the Agency can make a determination as to whether it is appropriate to regulate perchlorate in drinking water, we need to better understand total perchlorate exposure and what

portion comes from food versus water. Because perchlorate has been found in a variety of foods, we believe that a default assumption for the relative source contribution (RSC) (i.e., exposure to perchlorate from water as opposed to food sources) may not be the best means to determine whether it is appropriate to regulate perchlorate in drinking water. We need to determine how public exposure compares to the RfD and need to determine whether setting a drinking water standard would provide a meaningful opportunity to reduce risk for people served by public water systems. We described a number of approaches in our Federal Register Notice and asked for comment on their potential utility in informing a determination.

The FDA has been conducting surveys to determine perchlorate levels in food since 2004. EPA's May 2007 Federal Register Notice described results of FDA studies and other published studies of perchlorate levels in food. The FDA's Total Diet Study (TDS) provides the most comprehensive assessment of food exposure to date and is designed to provide estimates of total food exposure by region based on a representative market basket approach. In January 2008, FDA researchers published results of their analysis in the advance online version of the *Journal of Exposure Science and Environmental Epidemiology*. The study found detectable levels of perchlorate in 74 percent of the 285 TDS foods (Murray *et al.*, 2007). FDA estimated the average amount of perchlorate in the diet for 14 age-gender groups. The estimates range from 0.08 to 0.39 $\mu\text{g/kg/day}$, which is between 11 and 55 percent of EPA's RfD of 0.7 $\mu\text{g/kg/day}$. Estimates for infants and children are higher, on a body-weight basis, than those for teenage and adult subpopulation groups. FDA estimates that the majority (81%) of dietary perchlorate intake by infants comes from baby foods and dairy foods. The dairy group contributes about half of the total daily intake of perchlorate by children 2, 6 and 10 years of age. Vegetables and dairy foods combined account for between 46% and 59% of the total intake of perchlorate by teenagers and adults.

We are carrying out additional analyses to better understand what happens to perchlorate once it has been ingested by an infant or young child (e.g., how quickly is it excreted). Understanding these physiologic processes is critical to our evaluation of the effects of perchlorate exposure on these subpopulations.

We are continuing to carry out the analyses evaluating exposure that are needed to inform our regulatory determination and intend to issue a final regulatory determination before the end of 2008.

Trichloroethylene

While perchlorate is an emerging contaminant, trichloroethylene, or TCE, is a contaminant that the Agency has been regulating for several years. The Agency is carrying out several efforts related to TCE – developing a final risk assessment, reevaluating the regulations controlling TCE in drinking water, and evaluating the need for standards to manage risk from vapor intrusion at contaminated sites.

Reevaluating Risks

In 1989, EPA initiated a process to reevaluate the risk assessment for TCE through the Integrated Risk Information System (IRIS) process in response to uncertainties raised by an EPA Science Advisory Board (SAB) review regarding the appropriate classification for TCE carcinogenicity. The Agency subsequently engaged in an extensive scientific outreach effort to gather a diversity of views and range of expertise. The results of these efforts were used to prepare a draft risk assessment which in 2001 underwent public review and review by the SAB. The peer review report by the SAB was completed in 2002, but due to continuing science issues as well as significant emerging new science, in 2004, EPA, along with the Department of Defense, the Department of Energy, the National Aeronautics and Space Administration and Agency for Toxic Substances and Disease Registry, asked the NAS/National Research Council to provide independent guidance on scientific issues related to TCE. On July 27, 2006, the NAS/NRC publicly released its report on these science issues, providing advice to EPA.

Unlike the review of perchlorate, the NAS did not recommend an RfD or a cancer slope factor/unit risk for the Agency to consider. The panel recommended that EPA consider several issues as part of the risk assessment development process, including, for example:

- Development of a new meta-analysis of the epidemiologic data on TCE exposure and various forms of cancer, and
- Consideration of multiple options for dose metrics and benchmark response values when conducting dose-response analysis of cancer and non cancer endpoints.

- EPA has a multidisciplinary scientific team working on this assessment and has made this a top priority for its chemical assessment program. We currently expect to have an assessment ready for intra-agency review at the end of August and interagency review in December 2008. At this point in time, EPA is uncertain how extensive further review will need to be. This schedule is constrained by the complexity of the assessment, the size of the existing data base, and the recent availability of significant new information on modes of action relevant for TCE.

EPA's assessment team is addressing the NAS/NRC recommendations and comments previously received from all sources. Because of the complexity of this assessment, several sections of the assessment are being developed simultaneously.

Reevaluating Risk Management for Drinking Water

In 1987, EPA published a national primary drinking water regulation for TCE. The regulation established a Maximum Contaminant Level Goal (MCLG) of zero based on a cancer classification of B2, probable human carcinogen. EPA also set a Maximum Contaminant Level (MCL) of 0.005 mg/L, or 5 parts per billion (ppb), which was established based on analytical feasibility (i.e., the ability to measure the contaminant in water).

The 1996 SDWA Amendments require EPA to reassess national primary drinking water regulations every six years to determine if the regulations need to change. EPA completed its first Six Year Review in 2003 and made the decision to revise the Total Coliform Rule.

EPA is now carrying out the second Six Year Review process which will review existing national primary drinking water regulations for TCE and other regulated contaminants. As part of this review, we are analyzing new scientific and technological data and information on health effects associated with each regulated contaminant. With respect to TCE, the final risk assessment represents a key piece of information that will support any regulatory revisions. However, we are also evaluating technological information, including whether it is feasible for public water systems to reliably measure TCE in drinking water below the 5 ppb standard.

If the Agency identifies a potential health or technological basis for a revision to the drinking water regulation, this would necessitate a series of follow up analyses. For example, EPA would need to conduct an occurrence and exposure analysis to determine if changes to the drinking water standard are likely to increase public health protection for customers served by public water systems. EPA anticipates releasing the draft results of our Six Year Review for public comment in 2009 and completing our review in 2010.

Managing Vapor Intrusion

Vapor intrusion occurs when volatile chemicals in buried wastes and/or contaminated ground water migrate from the subsurface and emit vapors into air spaces of overlying buildings.

TCE is a prevalent ground water contaminant at hazardous waste sites throughout the country. While EPA has a TCE standard for drinking water, which is also used as a clean up goal for contaminated ground water, the Agency does not promulgate standards for vapor intrusion. A site specific risk assessment approach is used at sites to determine remediation goals.

EPA is developing recommendations for interim TCE toxicity values to assess human health risk and recommending an approach for vapor intrusion pathway analysis. Absent a toxicity value in EPA's Integrated Risk Information System (IRIS)(Tier 1 information), Agency guidance provides that provisional peer reviewed toxicity values be used (Tier 2 information), and if those are unavailable, other EPA and non-EPA sources of information (Tier 3 information) be used, with priority given to information which is transparent, publicly available, and has been peer reviewed. With respect to TCE toxicity, Tier 1 and Tier 2 information is not available, so the Agency must rely on Tier 3 information. To assist EPA regions, EPA is currently developing a recommended interim TCE toxicity value, based upon Tier 3 information.

With respect to the current management of vapor intrusion, EPA worked closely with the Interstate Technology & Regulatory Council (ITRC) to develop the ITRC's January 2007 guidance, *Vapor Intrusion Pathway: A Practical Guide*. The ITRC guidance improved upon prior EPA guidance by emphasizing the importance of evaluating multiple lines of evidence when determining the potential for vapor intrusion into buildings, and therefore we believe it is an appropriate starting point for vapor intrusion investigations and for assessing and managing vapor intrusion risks.

We will also continue the dialogue on the rapidly developing science of vapor intrusion with Federal partners, state regulators, industry, academia, environmental groups and the general public to continue to improve the science of vapor intrusion prevention.

Views on Proposed Senate Legislation

We have significant concerns with the bills introduced by Senators Boxer and Clinton. With respect to drinking water our primary concern with these bills is that they return the Agency to the time before 1996 when Congress dictated the drinking water regulations developed by the Agency. EPA found it difficult to meet the regulatory development requirements associated with the 1974 SDWA and 1986 Amendments, and stakeholders, including the states that implement SDWA requirements, almost universally questioned whether the Agency was able to focus its efforts on the most significant risks to health under this approach. In passing the 1996 Amendments, the intent of Congress was to bring a risk-based, scientifically sound approach to regulatory development. The changes that Congress made to the Act ensure that the Agency appropriately addresses contaminants that pose a risk to human health and develops regulations that provide a meaningful opportunity to reduce those risks from contaminants in public water supplies.

EPA has been working to carry out the activities required by the 1996 Amendments to evaluate unregulated drinking water contaminants and determine whether they require national regulation. In doing so, we review the best available, peer-reviewed science and supporting studies to determine if a contaminant poses a risk to human health. We collect and analyze information on contaminant occurrence, including monitoring the Agency itself may require or otherwise conduct, to determine if the contaminant occurs in drinking water at a level and frequency that may pose a risk to health. We also review information to determine if there are additional sources of exposure to a contaminant other than drinking water.

While our primary concern is that the bills would require regulation without considering the data and analyses that the Agency has spent the past several years developing, and thereby subvert the public process established by the SDWA to ensure that our regulatory activities are focused where they will provide the greatest public health benefit, we are also concerned about the

timeframes provided for by the bill. The SDWA provides the Agency with 24 months to propose a regulation after making a determination to regulate and another 18 months after proposal to issue a final rule. We believe this is the minimum time necessary to promulgate regulations that includes the analyses and public process required by SDWA and the Administrative Procedures Act and are sound enough to withstand judicial scrutiny.

Conclusion

The Agency is committed to robust protection of public health from contaminants in drinking water using the science-based framework laid out in the current SDWA. We are working expeditiously to address potential risks from perchlorate and to evaluate the need for and feasibility of a stronger standard for TCE using this framework. We believe this framework is sound, and respectfully request that you allow us time to complete the required analyses and determinations to ensure appropriate science-based protection of public health from these and other contaminants, as envisioned in the 1996 amendments. As noted above, we are committed to making a final regulatory determination for perchlorate by the end of 2008, and for TCE as soon as the necessary analyses have been completed.

Thank you again for this opportunity to describe EPA's important work on perchlorate and TCE. I would be happy to answer any questions you may have.